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FROM OMICS TO KNOWMICS

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Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: 2006D-0347 (for IVDMIA Draft Guidance)

Dear FDA Personnel:

As you are aware, the September 2006 issuance of the FDA's IVDMIA Draft Guidance document has prompted deep concern from many companies at the forefront of creating a new generation of personalization of medical therapies. Thank you for providing the extended period of time for us to collectively expand our dialogue with you, to give full consideration to the identification and explanation of our numerous concerns with this IVDMIA Draft Guidance, and to formally comment back to you on this.

The process of organizing our collective inputs and formulating responses led to the formation of a broad coalition of interested parties, from industry to patient advocacy groups, clinicians and others in a new organization known as the Coalition For 21st Century Medicine. Our company has participated as a founder and I have personally committed extensive time to the thoughtful development of policy and positions on behalf of the Coalition and our company, Target Discovery, Inc. The Coalition is providing a complete set of comments, covering all of the points that we collectively wish to make in response to the IVDMIA Draft Guidance document. I will not reiterate all of those points again here, but will point out that we echo and support all of those points as our own. However, I would like to take this opportunity to provide some personalization of concerns that are particularly specific and relevant to our company's experience.

I will offer some brief context on our company: Target Discovery, Inc. is developing a new generation of diagnostics focused upon the ability to discriminate and quantitate differences in individual isoforms of proteins at the post-translational modification level. The scientific literature has been accumulating considerable evidence pointing out that such isoform-level differences are frequently providing illuminating diagnostic insight and resolution, where other diagnostic biomarker strategies have proven inadequate or blind. Despite that fact that nucleic acid-focused strategies are served by the existence of convenient tool sets, and that many traditional proteomic strategies and companies have failed to thrive or survive, the potential of isoform-level diagnostics is emerging as a critical "missing link" in the pursuit of higher informing power from biomarkers. We have spent several years, funded by angel investors, creating new enabling technology and intellectual property for the identification, validation and commercial diagnostic

presentation of isoform-level diagnostics. We are now launching clinical collaborations with major cancer centers on our initial product development programs for personalized medicine applications. We are simultaneously in active pursuit of our first rounds of venture capital or other institutional funding to facilitate the development and commercialization of our initial personalized medicine diagnostic offerings. Our business model is based upon the commercially proven internal CLIA laboratory model, offering "home-brew" laboratory developed and validated tests (LDT's), utilizing the recognized advantages of speed in transitioning innovative discoveries through scientific and clinical validation and commercial introduction. In particular, this business model provides early access and facilitates progressive ongoing improvements to such innovative testing capabilities, for the clinicians working to guide patients and to personalize decisions on important therapy management questions.

The much-anticipated advent of "personalized medicine" is in fact dependent upon and is fundamentally the story of personalized medicine diagnostics. For many recent years, diagnostics has been broadly viewed as a business model with relatively little attraction for venture or institutional investors, given the time and investment required to develop what was frequently a relatively low margin business. The demonstration that companies like Myriad Genetics, Genomic Health and XDx could deliver important and innovative new personalized medicine diagnostics to the marketplace quickly and effectively through the internal CLIA lab and LDT model, and that they could receive appropriate value recognition and reimbursement for these innovations, was a paradigm-shifting breakthrough that refocused venture and institutional investors upon opportunities to participate in the realization of the promise of personalized medicine.

As the CEO of a young company investing great efforts into the development and leadership of the personalized medicine diagnostics arena, and simultaneously working to raise venture and other institutional capital for this effort, I can attest to the chilling impact that the FDA's IVDMIA Draft Guidance has had on fund-raising for this market and the pacing impact that this has on the forward progress of innovation. We are fortunate to enjoy warm relationships and dialogue with many venture capital investors, from which we have received consistent messages that they recognize and value our innovative focus and enabling technologies for the creation of isoform-level diagnostics, our initial market focus in high-value personalized medicine applications in oncology, and our selection of the proven CLIA lab and LDT business model. Since the September 2006 release of the FDA's IVDMIA Draft Guidance, these capital-raising conversations have been almost universally dampened by confusion and concern over the potential future involvement of the FDA in changing the investment and return outlook for this business model. It has certainly contributed to a substantially more conservative posture from investors concerning the attractiveness and appropriate timing and constraints for potential investments in this market. To accelerate important innovations in biomarker research and in the creation of personalized medicine diagnostics, this reversal in the investment environment needs speedy correction.

In summary, we have participated in the creation of and support all of the comments on the IVDMIA Draft Guidance that we have provided through the Coalition for 21st Century Medicine, as our own comments to you. In addition, I hope that this more personal perspective on our commitment to innovation in the achievement of personalized

medicine, and on the chilling investment impact that the Draft Guidance has injected into these efforts, will be of assistance to you in giving favorable consideration to our comments. If I may be of further assistance to you in discussing these matters in greater depth, I will be pleased to do so.

Respectfully,

Jeffrey N. Peterson
Chief Executive Officer